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10/598,334	08/24/2006	Leon Thomas Lee Marsh	78104113/N19108	2747

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EXAMINER
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DOUGHERTY, SEAN PATRICK

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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03/03/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,334	<b>Applicant(s)</b> MARSH, LEON THOMAS LEE	
	<b>Examiner</b> SEAN P. DOUGHERTY	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This is the Office action based on the 10/598334 application filed 08/24/2006.

#### ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Response to Amendment***

The amendment(s) filed 12/03/2009 by the Applicant in response to the previous Office action mailed 08/05/2009 have been considered by the Examiner. The Examiner acknowledges:

- Claims numbered 1-25 including:
  - Pending claim(s) 1-15 and 19-25;
  - Amended claim(s) 14;
  - New claim(s) 23-25; and
  - Cancelled claim(s) 16-18.

The Applicant's amendments have overcome the 35 U.S.C. 112 first paragraph rejection of claim 18 in the previous Office action.

The rejection(s) in the previous Office action of the claim(s), specifically in regards to the 35 U.S.C. 112 first and second paragraph rejections are maintained and expanded upon, below. The rejection(s) in the previous Office action of the claim(s),

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specifically in regards to the previously applied prior art are withdrawn and new ground(s) of rejection(s) is/are set forth below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 19-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-15 and 19-25 are rejected as the adequacy of the disclosure to enable a person of ordinary skill in the art to make and use the claimed invention is questioned by Examiner. Any person skilled in the art could not make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

The "formula" at para. 62 of the printed publication of the instant applicant is called into question by the Examiner. Specifically, the formula requirement of a "factor of ambient compensation".

The disclosure of the instant applicant suggests at para. 64 that the “factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade, and refers to the increase in the subjects core body temperature for every perfect loss of body weight, in temperate and hot climates respectively” and suggests at para. 43 “the factor of ambient compensation may be between 0.1 and 0.23 and is determined in dependence on the temperature of the environment surrounding the subject”.

It is important to note this is the only written explanation of the “factor of ambient compensation”.

The “factor of ambient compensation” is deemed simply a mythical number by the Examiner because it is beyond routine experimentation for one of ordinary skill in the art to determine how the factor is chosen. The logic behind exactly how the number is chosen is non-existent in the specification.

As stated above, the specification suggests that the “factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade” where the bounds of the factor of ambient compensation in centigrade are presented. The specification goes on to suggest the factor of ambient compensation “refers to the increase in the subjects core body temperature for every percent loss of body weight”. However, how this reference is made is non-existent in the disclosure. The disclosure lacks *how a reference is made*. By simply stating a reference is made, a skilled artisan would be required to perform undue experimentation to determine *how the reference is made*.

Similarly, the specification suggests that the “factor of ambient compensation may be between 0.1 and 0.23” where the bounds of the factor of ambient compensation

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are presented, without corresponding to any particular unit type. The specification goes on to suggest the factor of ambient compensation "is determined in dependence on the temperature of the environment surrounding the subject". However, how the determination is made and how the determination depends on the temperature of the environment surrounding the subject is non-existent in the disclosure. The disclosure lacks *how the determination is made and how the determination depends on the temperature of the environment surrounding the subject*. By simply stating a determination is made and that the determination depends on a temperature, a skilled artisan would be required to perform undue experimentation to determine *how the determination is made and how the determination depends on the temperature of the environment surrounding the subject*.

In summary, the disclosure of the instant application fails to enable how the factor of ambient compensation works or how it is chosen, therefore, it is beyond routine experimentation of one of ordinary skill in the art and a skilled artisan would not be able to make use of the invention. The "factor of ambient compensation" is not enabled by the original disclosure.

Claims 1-13 and 23 are indefinite as being too broad (undue breadth) because claim 1 is not supported by the original description or by an enabling disclosure. Claim 1 recites the limitation where a hydration level is calculated "in dependence on changes in the measured core body temperature", however, the Applicant's original disclosure sets forth that the hydration level is also calculated with other factors including a "subject's weight" and a "factor of ambient compensation" as established bridging pages 7 and 8

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and in the "formula" at page 7, lines 15-18 of Applicant's specification. One having an ordinary skill in the art at would not know what is included with the claims and what is excluded by the claims, when the claims are read in light of the specification because calculating a hydration level using just hydration level is not supported by the original description or by an enabling disclosure. A skilled artisan would find the bounds of the claim indefinite as it is not known if the limitations "subject's weight" and a "factor of ambient compensation" are included with claim 1 to provide a hydration level when the claim is read in light of the specification, because such limitations are required for calculating the hydration level. Furthermore, claims 1 is too broad because the "factor of ambient compensation" is not enabled by the original disclosure.

Claims 19-22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner notes that the Applicant was not in possession of hydration monitoring "without reliance on any measured electrical properties of the subject's body" as set forth in claim 19. The Examiner notes any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. Claim 19 does not have basis in the original disclosure and is being rejected for failing to comply with the written description requirement.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner notes that the Applicant was not in possession "only" obtaining measurements from the subject by an earpiece. The Examiner notes any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. Claim 21 does not have basis in the original disclosure and is being rejected for failing to comply with the written description requirement.

Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner notes that the Applicant was not in possession of calculating the hydration level "with reliance" or "independently from "the subject's heart rate". The Examiner notes any negative limitation or exclusionary proviso must have basis in the original disclosure. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). The mere absence of a positive recitation is not basis for an exclusion. Claims 23-25 do not have basis in the original disclosure and is being rejected for failing to comply with the written description requirement.



The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "measuring hydration of a subject in a hydration monitor" at lines 1-2 of claim 14 renders the claim indefinite. As currently written, it appears as if though the subject is intended to be "in" a hydration monitor. The Examiner assumes that the Applicant intends the preamble to claim that the calculation is performed in a hydration monitor.

Claims 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: a relationship between the hydration monitor and steps a-f. It is unclear to the Examiner if steps a-f are the preferred steps to be performed "in" the hydration monitor in claim 14. A relationship between the hydration monitor and the recited steps has not been established. Therefore, it is indefinite what purpose the hydration monitor serves and where and/or how steps a-f are performed, because a relation between the hydration monitor and the steps has not been established in claim 14. The Examiner also finds it indefinite if steps a and b are the only measuring steps, or if steps c-e are also including

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in the measuring steps. Steps a and b positively recite "measuring", however, steps c-e also are required to measure hydration, so they also appear to be measuring steps.

Claim 19 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: a relationship between the wearable temperature sensor and the processor. The claim fails to interrelate essential elements of the invention as defined by the Applicant in the specification, specifically the relation between the wearable temperature sensor and the processor.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 14 and 15 are drawn to process claims. The claims do not require that the process be implemented by a particular machine nor does the claim require that the method particularly transforms a particular article. Claim 14 recites calculations that are not implemented by a machine and could be performed mentally. Therefore, the process is not eligible subject matter because it is directed to non-statutory subject matter.

Claims 19-22 and 25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 19 positively recites

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limitations that overlap statutory classes. In this case, the applicant has positively recited a method and an apparatus in the same claim (e.g. a processor “calculating the subject’s hydration level”). See MPEP 2173.05(p) II.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 14, 15 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5 to 7,306,565 to Fraden et al. (hereinafter “Fraden”) in view of the publication titled “Effect of hypohydration on core temperature during exercise in temperate and hot environments” by Buono et al. (hereinafter “Buono”).

Regarding claims 1-12, 14, 15 and 19-25, Fraden discloses a monitoring comprising:

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- a temperature sensor (5) for measuring a subject's core body temperature and a processor (17), the processor being arranged to accept measurements from the temperature sensor (col. 1, ll. 23-24);
- an earpiece (4/6) worn on the ear and a remote unit (16), the temperature sensor being positioned in the earpiece for measuring the core body temperature via the subject's tympanic membrane (see Figure 1);
- where the temperature sensor comprises a thermopile (col. 4, ll. 4);
- where the earpiece further comprises a transmitter (col. 4, ll. 27), the remote unit including the processor (17), output means (19) and a receiver (23), the earpiece being arranged to communicate measurements to the processor via the transmitter and receiver;
- where the transmitter and receiver communicate wirelessly (26);
- where the transmitter and receiver are transceivers as demonstrated by wireless signal (26);
- where the remote unit comprises a monitoring apparatus (16);
- where the output means includes one or more of a display (19) and a speaker;
- arranged to operate repeatedly at predetermined intervals ("continuous" col. 1, ll. 23), the Examiner notes that continuous monitoring a predetermined interval;
- where the processor is arranged to generate an alarm, note that display (19) may be considered an alarm, as it is capable of alerting a user when core body temperature is not in an ideal range;

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- Fraden does not expressly disclose a memory for storing core body temperature, however, a skilled artisan would have found it obvious that processor (17) contains a memory for storing core body temperature, as computation of core body temperature would require a memory of some capacity to perform computation.

Fraden discloses the claimed invention as set forth and cited above except for where a hydration level is calculated in dependence on changes in the measured core body temperature, a processor being arranged to provide an indication of the hydration level via the output means, nor the steps of measuring an initial core body temperature of the subject, measuring a subsequent current core body temperature of the subject, subtracting the initial core body temperature from the subsequent core body temperature, thereby obtaining a difference, multiplying the difference by the subject's weight, thereby obtaining a multiplied difference, dividing the multiplied difference by a factor of ambient compensation, and multiplying the factor of ambient compensation by 100, thereby obtaining an indication of the subject's hydration level, where the factor of ambient compensation is between 0.1 and 0.23 and is determined in dependence on the temperature of the environment surrounding the subjection.

Buono is a reference that teaches hydration monitoring using a temperature sensor (Materials and methods: "sterile rectal probe") for measuring a subject's core body temperature (Materials and methods: "measure rectal temperature ( $T_{re}$ )") and accepting measurements from the temperature sensor and calculating a hydration level (Abstract: "Hypohydration increased  $T_{re}$  significantly ( $P < 0.05$ ) more in the hot

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environment (0.16 °C per 1% decrease in body mass) than in the temperate environment (0.08 °C per 1% hypohydration)”) in dependence on changes in the measured core body temperature (Results, see  $T_{re}$  section). Buoni teaches that temperature is indicative of hydration, therefore, the processor of Fraden, by simply displaying the temperature of the subject via display (19) is an indication of the hydration level. Buono teaches detecting changes in body temperature (Results, see  $T_{re}$  section), therefore, Buono teaches measuring an initial core body temperature of the subject, measuring a subsequent current core body temperature of the subject, subtracting the initial core body temperature from the subsequent core body temperature, thereby obtaining a difference. Buono teaches a factor of ambient compensation between 0.1 and 0.23 (“0.16 °C per 1% decrease in body mass”). Buoni teaches measuring a subject's weight (Materials and methods: “the subject's were weighed”). While Buono does not expressly disclose, multiplying the difference by the subject's weight, thereby obtaining a multiplied difference, dividing the multiplied difference by a factor of ambient compensation, and multiplying the factor of ambient compensation by 100, Buoni nonetheless uses similar factors (“the difference”, “subject's weight”) to achieve the same result of determining a hydration level based on core temperature measurements. It would have been an obvious matter of design choice to create the equation for determining hydration level as stated in the claims, since the prior art of Buono utilizes similar factors to achieve the same result - it appears the invention of Buono would perform equally as well for determining hydration level using temperature factors.

One having an ordinary skill in the art at the time the invention was made would have found it obvious to modify the temperature sensor of Fraden to employ the hydration monitoring of Buoni because Fraden teaches measuring core temperature using the ear temperature sensor would cause less discomfort and can remain in the ear for a long period of time for continuously monitoring core temperature (col. 2, ll. 25-27). A skilled artisan at the time the invention was made would have found an ear piece more comfortable than a rectal probe and more capable of continuous use for temperature, and thus, hydration monitoring. Therefore, a skilled artisan would have found the combination of references obvious.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5 to 7,306,565 to Fraden as modified by Buono, as applied to claim 1 above, and further in view of US 6,138,079 to Putnam.

Regarding claim 13, Fraden as modified by Buono discloses the claimed invention as set forth and cited above except for where the processor is arranged to generate an alarm upon determination of a hydration level below a predetermined level. Putnam is a reference that teaches an alarm that generates upon determination of a hydration level below a predetermined level (col. 3, ll. 22-27). One having an ordinary skill in the art at the time the invention was made would have found it obvious to modify the processor of Fraden as modified by Buono to include the capability of generating an alarm when a hydration level is below a predetermined level, because Putnam teaches at col. 1, ll. 8-9 that the alarm would provide athletes with information regarding effects

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of their exercise. Therefore, a skilled artisan would have found the combination of references obvious.

### ***Response to Arguments***

The Applicant's arguments filed 12/03/2009 have been fully considered by the Examiner, below:

The Applicant argues the rejection of claims 1-15 and 18 under 35 U.S.C. first paragraph at pages 6 to 8. The Applicant argues reconsideration of the rejections of claims "since one of ordinary skill can readily make and use the invention without undue experimentation". The Examiner disagrees and respectfully submits that undue experimentation would be required by a skilled artisan to make use of the invention. The "factor of ambient compensation" is deemed simply a mythical number by the Examiner because it is beyond routine experimentation for one of ordinary skill in the art to determine how the factor is chosen. The logic behind exactly how the factor of ambient compensation is chosen is non-existent in the specification. An (expanded) explanation of the Examiner's rationale is provided in the rejections, above.

The Examiner notes the Applicant's claim as how a skilled artisan could make use of the invention. However, the Applicant's arguments would present new matter if added to the specification. The disclosure does not enable the following points, as set forth in the arguments:

- readily setting the ambient compensation factor using the values of 0 degrees C and 30 degrees C;



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- the equation for determination the factor of compensation;
- the statement that the factor of ambient compensation is a scaling factor.

These statements are absent from the disclosure of the instant application and are beyond routine skill for one of ordinary skill in the art. These statements are not sufficient to show that they are routine in the art. The Examiner maintains that undue experimentation would be required by a skilled artisan to make use of the invention.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736